K022708

Premarket Notification 510(k) Summary

NOV 12 2002

Trade Name:	Klarity®
Common Name:	Thermoplastic (moldable)
FDA Classification Name:	Accelerator, Linear, Medical
Medical Specialty	Radiology
Product Code	IYE
Device Class	2
Regulation Number	892.5050
Applicant:	Larson Products, Inc. 2844 Banwick Road Columbus, OH 43232
Contact:	Peter M. Larson President Larson Products, Inc. (ph) 614-235-9100 (fax) 614-235-0004 email: plarson@larsonproducts.com
Date Prepared	July 9, 2002

- Klarity™ Thermoplastic is substantially equivalent to Aquaplast™ Thermoplastic, manufactured and sold by WFR Aquaplast Corporation, based in Lawlins Park, New Jersey. Aquaplast™ is registered under 510(k) Number K935067.

- Klarity™ is a "low temperature" Thermoplastic, which is pliant and moldable by hand when heated to a temperature of 155° F. (68° C.). Heating is best done by immersion in hot water.

- Klarity™ Thermoplastic is to be used by, or under the supervision of licensed physicians for the stabilization of patients undergoing external beam Radiation Therapy.

- Klarity™ Thermoplastic is to be sold in sheets of thickness from 1.6mm to 3.2mm, in a variety of dimensions chosen to be compatible with similar devices already in use.

- A common application of Klarity™ Thermoplastic will be as a "head mask" , where perforated thermoplastic is shaped around a patient's head and then firmly attached to a support board to hold the patient's head in a fixed position for repeat radiation therapy treatments.

- Klarity™ is equivalent to the predicate device in its chemical composition, method of manufacture, physical appearance, physical characteristics and intended use. The equivalence is verified by knowledge of the chemistry of the predicate device and physical testing. Physical testing includes detailed measurements of mass density, transmission of radiation, bolus effect, and comparison of moldability and shrinkage on simulated patient (wooden dummy).

- Use of "low-temperature" thermoplastics is commonly taught to all licensed U.S. Radiation Therapists, and these materials are in common use at Radiation Oncology clinics throughout the U.S. and the world.

- Safety, utility and medical effectiveness of these materials is affirmed by successful use of predicate device since 1982 for radiation therapy patient stabilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2002

Mr. Peter M. Larson
President
Larson Products, Inc.
2844 Banwick Road.
COLUMBUS OH 43232

Re: K022708
Trade/Device Name: Klarity Thermoplastic
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charge-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: August 12, 2002
Received: August 14, 2002

Dear Mr. Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022708

Device Name:

LARSON PRODUCTS, INC.
2644 BANWICK RD COLUMBUS OH 43232 (614) 235-9100 · FAX (614) 235-0004 · Email: info@larsonproducts.com
www.larsonproducts.com

STATEMENT OF INDICATIONS FOR USE

Klarity thermoplastic is intended for use by licensed physicians and trained radiation therapy professionals for the external support and stabilization of patients undergoing radiation therapy treatment in a licensed clinical setting.

Peter M. Larson date 8/8/02

Premarket Notification [510(k)] Number

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022708

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)